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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 08/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/815,379	GERRITSEN ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *5-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I in Paper No. 14 is acknowledged. The traversal is on the ground(s) that the restriction requirement was improper. This is not found persuasive because the inventions of the different groups are drawn to proteins, nucleic acids, antibodies, transgenic animals and methods of using the proteins, nucleic acids, and antibodies in screening. The inventions are considered distinct as indicated by their classification into different classes and subclasses. Furthermore, restriction is deemed proper because the search for the different inventions are not overlapping nor co-extensive, resulting in searches in distinctly different databases.

The requirement is still deemed proper and is therefore made FINAL.

2. Upon further review and reconsideration, it is noted that SEQ ID No: 2,4,6,8,10,12,14, and 16 are drawn to patentable distinct proteins, which are not related to one another by any common structure (i.e. not species of one another). Therefore, these proteins are consider separate inventions. During a telephone conversation with Gregory Zinkl on July 16, 2003 a provisional election was made with traverse to prosecute the invention of SEQ ID No: 4, claims 1-4. Affirmation of this election must be made by applicant in replying to this Office action.

3. Claims 1-41 are pending, claims 5-41 are withdrawn from further consideration as being drawn to a non-elected subject matter. Applicant is reminded to cancel all non-elected claims drawn to non-elected inventions.

4. Therefore, claims 1-4 are examined on the record to the extent that the claims read on SEQ ID No: 4. Applicant is reminded to amend the claims to reflect this election.

Information Disclosure Statement

5. The Information Disclosure Statement filed 1/7/2002 (paper no. 10) is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Objections

6. Claims 1, 3 and 4 are objected to because of the following informalities: the claims recite sequence identification numbers that are non-elected sequences. Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

7. Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. With regard to claim 2 and dependents thereof, in the recitation of the term "AAP", it is indefinite because of the utilization of an arbitrary protein name, "AAP". For example, others in the field may isolate the same protein and give it an entirely different name. Kojima S *et al.* (Anticancer Res. 2000 May-Jun;20(3A):1583-8) describe AAP as acetaminophen. Applicant should particularly point out and distinctly claim the "AAP" by

disclosing its full name. Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 112, 1st paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written in this case has only set forth the amino acid sequence of SEQ ID No: 4 and is not commensurate in scope to claims that read on sequences that are 80%, 90%, and 98% similar to SEQ ID No: 4.

The claims are drawn to an isolated polypeptide that is 80%, 90% and 98% identical to that of SEQ ID No: 4. However, there does not appear to be an adequate written description in the specification as-filed of the essential structural feature that provides the recited function of a polypeptide that is 80%, 90% or 98% identical to SEQ ID No: 4. The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e.,

structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Applicant does not appear to have reduced to practice any polypeptide, with exception to SEQ ID No: 4, that is 80, 90, or 98% identical to that of SEQ ID No: 4. Neither has Applicant provided a sufficient written description of any structure that may be correlated with the desired polypeptide. The genus of compounds encompassed by this term is extensive and the artisan would not be able to recognize that Applicant was in possession of the invention as now claimed.

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol.

66, No. 4, pages 1099-1111, Friday January 5, 2001. Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility.

The claims are drawn to an isolated polypeptide having 80%, 90%, and 98% percent identity to that of SEQ ID No: 4. The specification teaches that the instantly claimed polypeptide is "potentially useful in promoting wound healing", and further claims that the protein is useful for diagnostic, prognostic, pharmacogenomics, prophylactic methods and therapeutic methods. Specifically, SEQ ID No: 4 has been taught as a potentially useful marker and as a attractive target for various therapies to inhibit angiogenesis (see page 53). However, the specification has not taught to one of skill in the art that the claimed protein actually exists. The specification teaches that SEQ ID No: 4 is an ortholog of mouse BAZF gene and that hBAZF expression is upregulated in HUVEC during vessel formation. One of skill in the art would not be able to predict if SEQ ID NO: 4 is translated into a polypeptide expression product, or even if translated, whether it is overexpressed.

It is well known in the art that regulation of mRNA translation is one of the major regulatory steps in the control of gene expression (Jansen, M et al, 1995, Pediatric Res, 37 (6): 681-686). Those of skill in the art recognize that expression of mRNA, specific for a tissue type, does not dictate nor predict the translation of such mRNA into a polypeptide. For example, Alberts et al. (Molecular Biology of the Cell, 3rd edition, 1994, page 465) teach that translation of ferritin mRNA into ferritin polypeptide is blocked during periods of iron starvation. Likewise, if excess iron is available, the transferrin receptor mRNA is degraded and no transferrin receptor polypeptide is translated. Many other proteins are regulated at the translational level rather than the transcriptional level. For instance, Shantz and Pegg (Int J of Biochem and Cell Biol., 1999, Vol. 31, pp. 107-122) teach that ornithine decarboxylase is highly regulated in the cell at the level of translation and that translation of ornithine decarboxylase mRNA is dependent on the secondary structure of the mRNA and the availability of eIF-4E, which mediates translation initiation. McClean and Hill (Eur J of Cancer, 1993, vol. 29A, pp. 2243-2248) teach that p-glycoprotein can be overexpressed in CHO cells following exposure to radiation, without any concomitant overexpression of the p-glycoprotein mRNA. In addition, Fu et al (EMBO Journal, 1996, Vol. 15, pp. 4392-4401) teach that levels of p53 protein expression do not correlate with levels of p53 mRNA levels in blast cells taken from patients with acute myelogenous leukemia, said patients being without mutations in the p53 gene. Yokota, J et al (Oncogene, 1988,Vol.3, pp. 471-475) teach that the retinoblasma (RB) 115 kD protein is not detected in all nine cases of lung small-cell carcinoma, with either normal or abnormal size mRNA, whereas the RB protein is

detected in three of four adenocarcinomas and all three squamous cell carcinomas and one of two large cell carcinomas expressing normal size RB mRNA. Thus, predictability of protein translation or the extent of translation is not solely contingent on mRNA expression due to the multitude of homeostatic factors affecting transcription and translation. For the above reasons, one of skill in the art would not be able to predict if SEQ ID NO: 4 is translated into a polypeptide expression product, or even if translated, whether it is overexpressed.

Even assuming *arguendo*, that the protein is actually expressed and is upregulated, the specification has not taught a specific or substantial use for the polypeptide claimed. The claimed utilities for the claimed polypeptide is based on the assumption that the function of the said polypeptide is identical to that of the mouse ortholog. This correlation cannot be made based simply on homology alone because it has been established that protein similarity alone is not enough to base protein function. Stride *et al* (Mol Pharmacol. 1997 Sep;52(3):344-53) teach that when mouse or human orthologs of multidrug-resistance protein or MRP is transfected into HEK293 cells, the amount of drug resistance conferred by the human version of MRP was different from that of the mouse MRP, suggesting a "intrinsic difference between murine and human MRP orthologs." Therefore, given that orthologs can have different functions, the functions and potential utilities associated with the mouse BAZF cannot be accurately extrapolated to the human version.

The specification has not taught any association of SEQ ID No: 4 to any specific diseases, correlation to any diseases, or the etiology or involvement of disease. The

utilities disclosed are not specific nor substantial and can be applied to any isolated protein. Such utilities are not "specific" and would not constitute "substantial" real world applicability.

Claims 1-4 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Okabe *et al* (Mol Cell Biol 1998;18(7):4235-4244). Claims are drawn to an isolated polypeptide comprising a sequence having at least 80% identity with SEQ ID No: 4. The claims are further limited to and active AAP polypeptide. Okabe *et al* teach a peptide that has at least 80% identity to SEQ ID No: 4, and because the term AAP is considered a laboratory name associated with SEQ ID No: 4, the protein taught by Okabe *et al* is considered to be an active form of an AAP.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
July 24, 2003